



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/540,370

06/23/2005

Michael Jon White

27949A

2700

28880

7590

05/30/2008

PFIZER INC.

PATENT DEPARTMENT, MS8260-1611

GROTON, CT 06340

EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

05/30/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,370	<b>Applicant(s)</b> WHITE ET AL.	
	<b>Examiner</b> WALTER E. WEBB	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/08/2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Madyastha et al., (Applied Microbiology and Biotechnology 1995).

Madyastha et al. teach a steroid transformation of dehydroepiandrosterone (compound I) into 7-hydroxy-5-androsterone by contacting the compound I with *Mucor poriformis*. (See Abstract and Fig. 1.) The product is also isolated (see results at pg. 340.) They also show that the transformation process also yields a ketone at the 7th position and is capable of adding a hydroxyl group at position eleven of compound II. (See Fig. 1 at pg. 341.)

The reference anticipates the instant claims insofar as it teaches a process of preparing 7-hydroxy-5-androstene steroids with a species of Mucor where the 7-hydroxy-5-androstene steroid is isolated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madyhashta (*supra*) as applied to claim 1 above, and in view of Schmidt et al., (US 2,360,447) and in further view of Murray et al., (US 2,735,800).

Madyhashta differs from the instant claims 2-7 insofar as it does not teach contacting the hydroxyl steroid with bacteria to form the keto-steroid, nor does it teach using *Mucour rouxii* or *Mucor rouxii* ATCC4260.

Schmidt et al., teach a method of transforming an hydroxy steroid to a keto-steroid using *Alcaligenes faecalis* and *Escherichia coli* and isolating the keto-stroid by well-defined procedures. (See col. 1, lines 24-32, and col. 2, lines 25-40.) Here the hydroxyl at the 7th position is transformed to a ketone. (See illustration on page 2.)

Murray et al. teach a method of adding oxygen to a steroid molecule using the species of the *Mucor* genus. (See col. 1 lines 15-18, col. 4 lines 47-52, and col. 29

Art Unit: 1612

Table IX at col. 29, and lines 51-54.) Oxygen was added to position 11 of the steroids here but they teach that other positions may also undergo transformation due to the action of the fungus. (See col. 2, lines 40-42.)

It would have been obvious to a person having ordinary skill in the art to further transform the hydroxy steroid of Madyhashta to a ketone using the method of Schmidt. The artisan would be motivated to convert the steroid since Schmidt teach that ketosteroids are widely used as intermediaries or starting materials in the synthesis of many biologically active steroids, and keto steroids have biological activities not possessed by hydroxy steroids. (See col. 1, lines 23-32.) They also provide that certain hydroxy steroids have undesirable toxic properties. (See col. 2, lines 10-14.)

Further more the artisan would expect *Mucor rouxii* to perform the same function as *Mucor poriformis* given that *Mucor rouxii* as well as other species have been shown to transform steroids, as evidenced by Murray. A *Mucor rouxii* stored in the American Type Culture Collection (ATCC) with an assigned number 4260 would also be expected to transform steroids.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612